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JUN 14 1968
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1968

No. [redacted] 86

AMP INCORPORATED, *Petitioner*,

v.

WILBUR J. COHEN, Secretary of Health, Education and Welfare; and JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents*.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

REPLY TO BRIEF IN OPPOSITION

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REPLY TO BRIEF IN OPPOSITION

Respondents' counsel state, on page 9 of the "Brief For The United States In Opposition," that "the question involved here does not have the broad implications which petitioner endeavors to assign to it." This viewpoint conflicts squarely with that attributed to William

W. Goodrich, counsel to the Food and Drug Administration, as related in an article published in the Washington Post on June 8, 1968. The newspaper article was published on the assumption that certiorari had been denied in this case on June 3, 1968, an assumption that apparently arose as a result of a confusion of case captions. A copy of the article is appended hereto, together with a copy of a correction published in the same newspaper on June 9, 1968, explaining the confusion of caption.

Respectfully submitted,

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High Court Action Gives FDA Power To Regulate IUDs

By Morton Mintz
Washington Post Staff Writer

The Food and Drug Administration has won in the courts far-reaching new powers over medical devices that it has been unable to win on Capitol Hill.

The victory came Monday when the Supreme Court refused to review a little-noticed case involving products for a new method of tying off severed blood vessels during surgery.

The products were a disposable applicator, a nylon ligature loop and a nylon locking disk.

The manufacturer, AMP Inc., of Harrisburg, Pa., took the position that they were "devices" and thus did not require clearance by the FDA as safe and reliable before being put on sale.

The position taken by the FDA, on the advice of its counsel, William W. Goodrich, was that the products were legally "new drugs" and therefore could not be sold until their safety and efficacy had been demonstrated to the agency.

It argued that any products used to diagnose, prevent or treat disease legally fell under the more stringent procedures governing "new drugs" rather than the weaker controls regulating "devices."

The FDA position was sustained by Federal Judge Charles H. Tenney in New York City and, last Feb. 13, by the Second Circuit Court of Appeals.

In an opinion for an unanimous, 3-judge panel of the Appellate Court, Judge J. Joseph Smith said that the purpose of Congress in defining "devices" separately in the Food, Drug, and Cosmetic Act of 1938 was "to avoid the incongruity of classifying such things as electric belts as 'drugs.'"

But Congress "very, very clearly" intended to keep out of interstate commerce inadequately tested medical and related products which might cause widespread danger to human life," Judge Smith said. AMP then requested the review by the Supreme Court, which was denied.

Until now, the FDA has been able to act against unsafe and worthless medical devices only after they have been marketed—and undertaking complicated, slow legal actions.

The Supreme Court's denial of AMP's request revolutionizes the situation for a great number of products, ranging from nails used in bone repair to artificial eyes.

Now, counsel Goodrich said, the agency has power to require that, like drugs, they be cleared for safety and efficacy before being sold.

In addition, he said, the FDA now will have the same powers for articles that affect any of the bodily functions. Thus, Goodrich said, the FDA will be able to regulate before sale intra-uterine birth control devices, which are used by possibly 1 million women in this country and by 6 to 8 million in others.

Last January the FDA's Advisory Committee on Obstetrics and Gynecology said needless hazards to life and health are being caused by IUDs of "closed" design and by carelessness about the possibility of infection during insertion.

The FDA Committee, headed by Dr. Louis M. Hellman, said that "closed" designs—including rings, bows, hearts and butterflies—should almost never be used.

The Committee found that although just one "open" type of IUD was a hundred times more widely used than all the "closed" shapes combined, a survey showed not a single case of perforation of the uterus in women using "open" models. In contrast, 13 cases were reported in the much smaller group using the "closed" designs—and surgical removal of the IUD was required in most or all of the cases.

Drug Ruling Report Was In Error

The Supreme Court still has pending before it a request for review of a lower court decision declaring certain medical devices to be legally "new drugs."

This request has not been acted on, contrary to a story in Saturday's editions of The Washington Post.

The error grew out of the fact that the petitioner, AMP, Inc., of Harrisburg, Pa., had requested review of decisions in two separate, unrelated cases.

Last Monday, the Supreme Court denied review in a case in which the defendant is the United States. In the second case Wilbur Cohen, Secretary of Health, Education, and Welfare, and James L. Goddard, Commissioner of the Food and Drug Administration, are the named defendants.

The Washington Post regrets the error.